IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL NO. 2804
	Civ. No. 1:17-md-02804-DAP
THIS DOCUMENT RELATES TO: *Track One Cases*	HON. JUDGE DAN A. POLSTER

OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE

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I. INTRODUCTION

The Omnibus Memorandum Of Law In Support Of All Track One Bellwether Trial Defendants' Motions In Limine contains an overview of the controlling law governing motions in limine. AmerisourceBergen, Cardinal Health, McKesson, and Henry Schein (collectively, "Distributors") incorporate that discussion here.

II. IN LIMINE RULINGS REQUESTED

1. [D-1] The Court Should Preclude Plaintiffs From Offering Evidence Of, Or Arguments About, Distributors' Settlements With The DEA And West Virginia

Between 2007 and 2017, AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, and McKesson each entered into one or more settlement agreements with the U.S. Drug Enforcement Administration. They also entered into settlements with the State of West Virginia in 2017 and 2019. Throughout this litigation, Plaintiffs have repeatedly cited these civil and administrative settlement agreements as evidence that Distributors failed to comply with a purported duty to report and block suspicious orders and, as a consequence, Defendants are liable to Plaintiffs. The Court should exclude any evidence of, reference to, or arguments about these settlements because they are inadmissible under (1) Rule 408 of the Federal Rules of Evidence, which prohibits the use of settlement evidence to prove the validity of disputed claims, (2) Rules 401 and 402, because they irrelevant since they do not concern Distributor facilities that serviced Summit and Cuyahoga counties, and (3) Rule 403, because the any minimal probative value the settlements might have (and there is none) is far outweighed by the unfair prejudice that would result if the jury were exposed to these settlements.

Background. In every iteration of their Complaints, Plaintiffs allege that Distributors did not maintain effective controls against diversion in connection with their distribution of controlled substances to pharmacies in Cuyahoga and Summit counties. More recently, in their

Motion for Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under The Federal Controlled Substances Act (Dkt. No. 1910), Plaintiffs sought a ruling that Distributors violated certain duties under the Controlled Substances Act ("CSA") and implementing regulations—in particular, 21 C.F.R. § 1301.74—regarding suspicious order monitoring. *See* Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 2 (arguing that "[t]he Court can and should find, based on the undisputed evidence, that each of the Defendants repeatedly violated the Controlled Substances Act in their shipments to Summit and Cuyahoga Counties."). In support of that contention, Plaintiffs repeatedly cited Distributors' prior settlements with DEA. *See*, *e.g.*, Dkt. No. 1910-1 at 69-71, 81-82, 88, 93, 105-11, 113, 119-122.

Three of the six DEA settlements, however, contain no admissions of wrongdoing. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Three others contain narrow admissions that do not implicate the Track One Plaintiffs or their claims. In its 2012 Memorandum of Agreement (MoA), "Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." Dkt. No. 1960-103 (Ex. 209) at 3. The 2012 MoA does not identify what those failures were, when or where they occurred, or whether the inadequacies were violations of the CSA. In its 2017 Settlement, McKesson acknowledged that "at various times" from January 2009 to January 2017 "it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 8942(a)(5)." Dkt. No. 1964-24 (Ex. 236). None of the settlements has anything to do with distributions of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

The same is true of Cardinal Health's 2016 settlement with West Virginia, ABDC's 2017 settlement with West Virginia, and McKesson's 2019 settlement with West Virginia: they expressly disclaim any admission of wrongdoing.

The Settlements Are Inadmissible Under Rule 408. Admission of evidence or arguments about the settlements would contravene both the text and purpose of Rule 408, which "bars the admission of settlement agreements when offered 'to prove or disprove the validity or amount of a disputed claim.'" *United States v. Tevis*, 593 F. App'x 473, 476 (6th Cir. 2015) (quoting Fed. R. Evid. 408(a)(1) (evidence of "accepting . . . a valuable consideration in compromising . . . [a] claim" is "not admissible . . . to prove . . . the validity or amount of a disputed claim")); 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 408.03[5] (2d ed. 2017) ("Rule 408 applies . . . to completed compromises when offered against a compromiser."). "The purpose of this rule is to encourage settlements which would be discouraged if such evidence were admissible." Fed. R. Evid. 408 advisory committee notes, 1974 Enactment; *see Eid v. Saint-Gobain Abrasives, Inc.*, 377 F. App'x 438, 444 (6th Cir. 2010).

Under Rule 408, evidence of both the existence and content of prior settlement agreements is inadmissible for purposes of proving liability on a later civil claim. For example, in *Hobart Corporation v. Dayton Power & Light Co.*, No. 3:13-cv-115, 2017 WL 5956911 (S.D. Ohio Nov. 30, 2017), the court rejected plaintiffs' effort to establish that the defendant had assumed certain environmental liabilities because its corporate predecessor had made certain "admission[s]" in a settlement agreement resolving a separate case involving a different site. *Id.* at *19-20. Because the plaintiffs were "attempting to use evidence of a prior settlement agreement to establish . . . liability and prove the validity of a disputed . . . claim," the court held that the evidence was "inadmissible under Rule 408." *Id.* at *21. As the court explained,

"making the content of prior settlement agreements available for use in related litigation contravenes the very purpose of Rule 408." *Id.*

Likewise, in *Massachusetts Mutual Life Insurance Co. v. DLJ Mortgage Capital, Inc.*, 251 F. Supp. 3d 329 (D. Mass. 2017), the court precluded the plaintiff from relying on "certain facts set forth and acknowledged by Credit Suisse in a settlement agreement" with the Department of Justice to establish liability. *Id.* at 331. "[T]he letter, policy, and development of Rule 408" demonstrated that the DOJ settlement agreement, including the statement of facts expressly acknowledged by Credit Suisse therein, was "inadmissible" to establish liability. *Id.* at 332; *see also*, *e.g.*, *City of Mishawaka v. Uniroyal Holding, Inc.*, No. 3:04-cv-125, 2009 WL 499105, at *5 (N.D. Ind. Feb. 26, 2009) (rejecting plaintiff's attempt to use "prior settlement agreements" to "establish . . . liability by admission" because such a use of the agreements would be "precisely for the reasons prohibited by [Rule 408]").

Plaintiffs here clearly intend to rely on the settlements to prove Distributors' alleged failure to maintain adequate controls against diversion. *See*, *e.g.*, Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 20 (arguing that "a finding from this Court" that Distributors "shipped opioids in violation of the CSA has consequences for particular elements of many of Plaintiffs' claims"). Because the settlements represent the acceptance of a compromise of disputed claims, Plaintiffs' attempt to use the settlements to establish liability in the present cases is barred by Rule 408.[1] That is reason enough to bar any evidence of, reference to, or arguments about the settlements.

The Settlements Are Irrelevant Under Rules 401 And 402. The settlements also are irrelevant to Plaintiffs' claims and, therefore, are inadmissible under Rules 401 and 402. To

[1] Although Plaintiffs do not offer settlements for purposes of establishing the amount of damages they seek to recover, Rule 408 would bar their admission for that purpose as well. *See* Fed. R. Evid. 408(a)(1) (evidence of "accepting . . . a valuable consideration in compromising . . . [a] claim" is "not admissible . . . to prove . . . the validity *or amount* of a disputed claim") (emphasis added). Distributors reserve the right to object at trial if Plaintiffs seek to introduce the DEA Settlements to establish the amount of their claims or for any other purpose.

establish relevance, Plaintiffs must show that evidence of the settlements make any "fact . . . of consequence" in these cases "more or less probable than it would be without the evidence." Fed. R. Evid. 401 (test for relevant evidence); *see also* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). To begin with, three of the six settlements with the DEA expressly disclaim any admission or concession of liability. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Of the three agreements that do contain narrow admissions, *none* implicates distribution of opioids into Summit and Cuyahoga counties.

- Cardinal's 2012 MoA arose out of a DEA investigation of seven specific facilities in California, Colorado, Florida, Georgia, New Jersey, Texas, and Washington, Ex. 215 at 1-2—*none* of which distributes to Ohio pharmacies. The MoA mentions Cardinal Health's Ohio facilities only as part of a list of facilities ***not*** investigated. Ex. 215 at 13.

- McKesson's 2017 settlement contains allegations relating to twelve distribution centers, none of which is the New Castle, PA facility that services Summit and Cuyahoga counties. The settlement also does not identify any particular pharmacies or shipments in Ohio, nor are there any admissions concerning McKesson's operations in Ohio.

- Neither ABDC's April 19, 2007 Initial Suspension Order nor the June 22, 2007 Settlement Agreement contains allegations concerning distribution of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

Similarly, Cardinal Health, ABDC, and McKesson's settlements with West Virginia neither admit fault nor concern shipments of prescription opioids to any place other than West Virginia.

And, notwithstanding the narrow admissions contained in three of the settlements, the agreements are not relevant, because any reference to them would necessarily depend on a "if it happened there, it must be happening here" premise—which is, as Plaintiffs have acknowledged, invalid. Dkt. No. 2212 at 9, 30 (citing *In re Chocolate Confectionary Antitrust Litig.*, 801 F.3d 383, 402 (3d Cir. 2015) (quoting Areeda & Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF

ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 1421a, at 160); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 51-52 (2d Cir. 2007)).

The narrow admissions are also irrelevant because they do not establish any element of Plaintiffs' claims. For the RICO claims, Plaintiffs must establish (inter alia) a *knowing or intentional* violation of the CSA statute—and none of the settlements admits to any such knowing or intentional wrongdoing.[2] Similarly, for the nuisance claim, violation of the CSA is irrelevant because the CSA is not a safety statute.[3]

The Settlements Are Inadmissible Under Rule 403. Even if the settlements had some relevance (which they do not), they still would be inadmissible under Rule 403, which requires the exclusion of evidence "if its probative value is substantially outweighed" by the "danger" of "unfair prejudice" or "confusing the issues." Fed. R. Evid. 403. Admission of the settlements would unfairly prejudice the Distributors and cause jury confusion. As the Sixth Circuit has explained, "the potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound" and would, if allowed, undermine the "'strong public interest' in encouraging settlement negotiations." *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 800, 805 (6th Cir. 2007) (quoting *Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 332 F.3d 976, 980 (6th Cir. 2003)).[4]

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[2] 21 U.S.C. §§ 841, 843 ("[I]t shall be unlawful for any person knowingly or intentionally . . . ."); *see* 18 U.S.C. § 1961(1)(D) (predicate acts limited to "felonious" conduct).

[3] *Taylor v. City of Cincinnati*, 143 Ohio St. 426, 433 (1944) (a statute is a "safety statute" only if it sets forth a "specific legal requirement for the protection" of the plaintiff and those similarly situated); *see* Opinion & Order (Dkt. No. 1680) at 24 (CSA "was not intended to protect [governments] from spending more on addiction-related public services").

[4] Underscoring both the importance of the bar on the admission of settlement agreements, the Sixth Circuit has explained that the public interest in settlement negotiations would be undermined if settling parties enjoyed only thin "veneer of protection" offered by curative instructions. *Id.* at 805. The Court, accordingly, has "reject[ed] the proposition that any amount of evidence supporting liability, . . . coupled with a limiting instruction read at any time during the trial is sufficient to cure the wrongful admission" of settlement evidence. *Id.*; *see also* 2 Jack B. Weinstein & Margaret A. Berger, *Weinsten's Federal Evidence* § 408.11[1][a] (2d ed. 2017) ("The failure to

2. [D-2] The Court Should Preclude Non-Party Corporate Representatives From Testifying To Matters Outside Their Personal Knowledge

The Court should preclude Plaintiffs from offering testimony, whether live or by deposition, of non-party corporate representatives (Rule 30(b)(6) witnesses) on matters outside the witnesses' personal knowledge. This bar should extend to testimony based on hearsay conversations with other employees, review of documents, and other sources consulted by the witness to prepare to testify as a corporate representative. Information derived from such sources is properly offered in discovery under Rule 30(b)(6), but it is not admissible at trial.

Several examples arose in the Rule 30(b)(6) deposition of DEA employee Thomas Prevoznik. Mr. Prevoznik joined the DEA 28 years ago. See Prevoznik Tr. (Dkt. No. 1983-9) at 26:13-14, 42:15-17; 83:2-5. But he testified regarding events and documents that predated that period, such as a report compiled in 1987. *See* Prevoznik Tr. (Dkt. No. 1983-11) at 803:16-806:4. He also testified more generally about matters of which he had no personal knowledge. For example, Mr. Prevoznik identified a document as a presentation made by the DEA after admitting, "I've never seen this before." *Id.* at 981:15-986:5.

At trial, a lay witness's testimony is limited to matters within his or her personal knowledge. Fed. R. Evid. 602. The witness's own testimony may be used to provide evidence proving such personal knowledge exists. *Id.* But that testimony still is subject to the hearsay restrictions in Rules 801 and 805. Fed. R. Evid. 602 advisory committee's note.

This rule does not change for a non-party 30(b)(6) witness.[5] The 30(b)(6) designation "does not create a hearsay exception allowing him [at trial] to simply repeat statements made by corporate officers and employees, if those statements are offered for their truth." *Cooley v.*

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exclude evidence of an offer or a completed agreement . . . is sufficiently prejudicial to warrant a mistrial, even if there has been an admonition.").

[5] Deposition testimony given by a ***party*** under Rule 30(b)(6) may under some circumstances be admissible against that party as a party admission. This motion focuses on ***non-party*** 30(b)(6) testimony.

Lincoln Elec. Co., 693 F.Supp.2d 767, 791 (N.D. Ohio 2010). The prohibition on using 30(b)(6) witnesses as conduits for hearsay is especially important when the proponent does not offer any "independent evidentiary basis that might otherwise prove the truth of the hearsay." *Id.* at 792.

Although Rule 30(b)(6) gives broad latitude for the representative to speak about corporate knowledge at a deposition, that right is significantly narrowed by the hearsay rule that applies *at trial*. "[A] corporate representative may not testify to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.'" *Union Pump Co. v. Centrifugal Technology Inc.*, 404 F. App'x 899, 907-08 (5th Cir. 2010) (quoting *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 435 (5th Cir. 2006))).

Therefore, while plaintiffs may offer otherwise admissible testimony from Mr. Prevoznik or other third-party 30(b)(6) designees that reflects their own personal knowledge, testimony that is not based on personal knowledge is hearsay and lacks foundation and is therefore inadmissible.

3. [D-3] The Court Should Exclude Any Evidence Of Criminal Indictments And Investigations Without Corresponding Proof Of A Final Judgment Of Conviction

Plaintiffs' proposed exhibit list includes indictments (as well as press releases announcing indictments) that allege misconduct in the distribution, prescription, and dispensing of opioid medications. The fact that someone has been indicted amounts to "no more than an accusation, *i.e.*, alleging that the defendant committed the crime." 3 Fishman & McKenna, *Jones on Evidence* § 17:34 (7th ed.); *see also, e.g.*, *Ruffalo's Truck. Serv. v. Nat'l Ben-Franklin Ins. Co.*, 243 F.2d 949, 953 (2d Cir. 1957) ("The indictment, since it was only hearsay, was clearly inadmissible for any purpose."); *United States v. Olivieri*, 740 F. Supp. 2d 414, 419 (S.D.N.Y.

2010) ("Charging Instruments are hearsay."). The Court should therefore exclude these exhibits, related testimony and press releases, and any other evidence concerning criminal indictments.[6]

To be sure, an indictment may be introduced "under Rule 803(22), which excepts judgments of previous *convictions* from the general ban against hearsay." *Mike's Train House, Inc. v. Lionel, LLC,* 472 F.3d 398, 412 (6th Cir. 2006) (emphasis added). But to satisfy this exception, plaintiffs would need to present a corresponding *judgment of conviction* that meets the strictures of Rule 803(22), including that the judgment be final and entered after a trial or guilty plea. *See id.* The point remains that a mere indictment will not suffice. *Cf. Munsey v. Tactical Armor Prods., Inc.*, No. 07-CV-445, 2008 WL 4500130, at *1 (E.D. Tenn. Sept. 30, 2008) ("The Court agrees with defendants that the Superseding Indictment is hearsay that does not fall within any hearsay exception."). Indeed, the fact that an indictment might satisfy a hearsay exception *when accompanied by a corresponding conviction* only underscores the default rule that an indictment standing alone is inadmissible. *See Gritton*, 2007 WL 3407459, at *10 ("Absent a conviction, it follows that these indictments do not come within the scope of Rule 803(22) and remain inadmissible hearsay."). And even such a conviction is admissible only if admitted to prove a fact "essential to the judgment." Fed. R. Evid. 803(22)(C).

Even if plaintiffs purport to offer an indictment for reasons other than the truth of its underlying allegations, the indictment would be inadmissible under Rule 402. The mere fact that the government has indicted someone has no relevance independent of the truth of the underlying allegations, given that "an indictment is not *any* evidence of guilt." *United States v. Chance*,

[6] The general bar against admitting criminal indictments carries special force because "indictments may be issued where the entire basis of evidence against the criminal defendant is hearsay." *Gritton v. Disponett*, No. 3:05-cv-75-JMH, 2007 WL 3407459, at *10 n.12 (E.D. Ky. Nov. 14, 2007). In other words, not only are indictments themselves hearsay, they may rest on nothing but hearsay—further compounding their unreliability. Given those shaky foundations, "there are no circumstantial guarantees of trustworthiness which would render [criminal indictments] admissible under the residual exception." *Levinson v. Westport Nat. Bank*, Nos. 09cv269(VLB), 09–cv–1955(VLB), 10cv261(VLB), 2013 WL 2181042, at *1 (D. Conn. May 20, 2013).

306 F.3d 356, 385 (6th Cir. 2002) (emphasis added); *see also In re Knerr*, 361 B.R. 858, 862 (Bankr. N.D. Ohio 2007) (striking state court indictment "[b]ecause an indictment is not evidence of any kind against a defendant and does not create any presumption or permit any inference of guilt" (internal quotation marks and citation omitted)). The only relevance of an indictment depends on the truth of its allegations. And because "indictments do not prove that any of the conduct described therein actually occurred," they should be excluded as irrelevant. *Chen v. Mayflower Transit, Inc.*, 315 F. Supp. 2d 886, 923 (N.D. Ill. 2004).[7] Despite the lack of any probative value, introduction of indictments would also create a substantial risk of unfair prejudice, as an "indictment's official nature" lends an undeserving imprimatur of credibility to its allegations that risks misleading and confusing the jury. *Baxter Health Care Corp. v. Spectramed Inc.*, No. SA CV 89-131, 1992 WL 340763, at *3 (C.D. Cal. Aug. 27, 1992).

The grounds for excluding evidence of ongoing criminal investigations are equally compelling. Like an indictment, the mere existence of a criminal investigation is not evidence admissible against a defendant. Even if an ongoing criminal investigation could be deemed to have some minimal probative value, that probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury—and thus should be excluded under Rule 403. *See Spencer v. McDonald*, 705 F. App'x 386, 390 (6th Cir. 2017) (affirming decision to exclude evidence of a criminal investigation because "[e]ven if the investigation were relevant" to the issues in the civil case, the district court did not abuse its discretion in excluding it under Rule 403); *Park W. Galleries, Inc. v. Glob. Fine Art Registry, LLC*, Nos. 08–cv–12247, 2:08–cv–12274, 2010 WL 848689, at *1 (E.D. Mich. Mar. 8, 2010) (excluding evidence of an FBI investigation under Rule 403 because "'[t]he probative value of

[7] Many of the indictments on Plaintiffs' list are also irrelevant because they relate only to allegations occurring outside of the Plaintiff counties.

an ongoing criminal investigation is substantially outweighed by the danger of unfair prejudice, confusion of the issues and misleading the jury'") (quoting *Fidelity Nat'l Title Ins. Co. of N.Y. v. Intercounty Nat'l Title Ins. Co.,* Nos. 00 C 5658, 00 C 7086, 2003 WL 2005233, at *10 (N.D. Ill. Apr. 30, 2003)). Rule 403 applies not only to documents and testimony on direct examination, but also to questions on cross-examination. *See United States v. Newsom*, 452 F.3d 593, 602-04 (6th Cir. 2006) (agreeing that "the district court erred in allowing the government to cross-examine his other witnesses . . . because the resulting evidence violated Rule 403"); *Spencer*, 705 F. App'x at 392 (affirming the disallowance under Rule 403 of an impeachment question on cross-examination regarding a criminal investigation).

For these reasons, the Court should exclude any evidence of criminal investigations or indictments without corresponding proof of a final judgment of a conviction.

4. [D-4] The Court Should Prohibit Plaintiffs From Stating Expressly Or Suggesting That The Jury May Infer That An Older Document Never Existed Just Because It Cannot Be Found

At his deposition, Plaintiffs' DEA expert James Rafalski offered his opinion that customer due diligence records and suspicious order reports "should be kept forever."[8] Then, in forming his opinions about alleged violations of the Controlled Substances Act, he assumed that if a distributor is unable to locate a due diligence file, this means the due diligence was not performed, even if the file would have been created in 1996, more than twenty years ago.[9] This assumption is the sole basis for Rafalski's conclusion that there was a "complete failure" by

[8] Rafalski Tr. (Dkt. No. 1983-15) at 125:5–126:3;

[9] *Id*. at 289:10-17.

Defendants to perform due diligence on customer orders[10] and is the basis on which Craig McCann, Plaintiffs' data expert, flagged all but a tiny percentage of orders as suspicious.[11]

The fact that suspicious order reports and due diligence files from five, ten, or twenty years ago cannot be located today does *not* mean they never existed. The Court should preclude Plaintiffs and their experts from drawing or suggesting this inference for two reasons: (1) it is contradicted by 30(b)(6) testimony from DEA and inconsistent with the CSA's record retention regulations, which impose no requirement to retain these records for any period of time, let alone "forever"; and (2) it does not satisfy the adverse inference test, as applied in the Sixth Circuit.

Inconsistent with DEA Testimony and the CSA. DEA's 30(b)(6) representative, Thomas Prevoznik, testified that there is no requirement to retain suspicious order reports that are submitted to DEA, and "there's no requirement that a due diligence file even be maintained."[12] That testimony is consistent with the record retention requirements outlined in Part 1304 of the CSA regulations, which governs records and reports. Those regulations impose several, explicitly defined recordkeeping requirements for certain categories of documents—*e.g.*, invoices, packing slips, inventories and records of controlled substances, paper and electronic prescriptions, and distribution records, *see* 21 C.F.R. §§ 1304.04, 1304.06, 1304.22—but impose *no* requirement that registrants retain suspicious order reports and due diligence documents at all, let alone "forever." For the specified records that must be retained, the regulations state that "every inventory and other records required to be kept under this part must be kept by the registrant and be available, for a period of *at least 2 years* from the date of such inventory or

[10] *Id*. at 188:2-10 ("It's not an assumption. It's based on my review of records and depositions and documents that I couldn't find a time period where I believed there was sufficient due diligence . . . there was actually a complete failure.").

[11] Expert Report of Craig McCann (Dkt. No. 1965-65) at 56-57.

[12] Prevoznik Tr. (Dkt. No. 1983-11) at 1219:1-4; 1220:20–1221:1.

records for inspection and copying by authorized employees of the Administration." 21 C.F.R. § 1304.04(a) (emphasis added); *see* Rafalski Tr. (Dkt. No. 1983-15) at 124:18-24 ("Any of the records that are in the records section of the CFR have a *two-year retention*") (emphasis added). Other than the requirements in Part 1304, the CSA imposes no other document retention requirements, including for suspicious order reports and due diligence documentation. Neither the CSA nor its regulations even mention due diligence documentation, let alone impose a record retention requirement. *See* Rafalski Tr. (Dkt. No. 1983-15) at 128:14-18 ("The CFR doesn't speak specifically to a due diligence record . . . .").

The inference that if a record presently does not exist, it never did, is a significant driver of Rafalski's assessment of Defendants' alleged failures, but he offers no basis for it other than a vague allusion to his experience, training, and knowledge.[13] He acknowledges that suspicious order reports and due diligence documentation are not subject to the two-year retention requirement in Part 1304,[14] but nevertheless maintains that if a registrant does not keep these documents indefinitely, it violates the requirement to "maintain effective controls against diversion."[15] Because that conclusion is contrary to the official testimony from DEA's designee, and has no basis in the CSA's record-retention requirements, the Court should preclude Plaintiffs from relying on this inference at trial.

Unsupportable Inference According to Sixth Circuit Test. The Sixth Circuit has established a three-prong test that must be met before the Court may order an adverse inference instruction based on the destruction of evidence. *Stocker v. United States*, 705 F.3d 225, 235 (6th Cir. 2013). Plaintiffs cannot meet this test. *First*, the moving party must establish "that the

[13] Rafalski Tr. (Dkt. No. 1983-15) at 172:5-12.

[14] *Id*. at 125:5-13;

[15] *Id.* at 128:7-18;

party having control over the evidence had an *obligation to preserve it* at the time it was destroyed." *Id*. (emphasis added) (internal quotation marks omitted). Because Defendants did not have an obligation to preserve suspicious order reports and due diligence records, including documents dating as far back as 1996, there is no basis to infer that their failure to retain the documents is evidence that they never existed. *Second*, the moving party must show "that the records were destroyed with a culpable state of mind." *Id.* (internal quotation marks omitted). Even if the Court were to credit Rafalski's testimony that Defendants had an obligation to maintain due diligence documentation "forever," Plaintiffs have no evidence that Defendants destroyed the records with a culpable state of mind.

5. [D-5] The Court Should Prohibit Plaintiffs From Presenting Evidence Or Making Arguments Suggesting Distributors Committed A "Fraud On The DEA"

The Court should bar Plaintiffs from presenting testimony, offering other evidence, and making arguments to the jury suggesting that Distributor Defendants engaged in a "fraud on the DEA."

Plaintiffs have disclaimed pursuing claims based on a "fraud on the DEA" theory; and, regarding Plaintiffs' deceptive marketing theories, the Court has held that they do not concern fraud on the DEA. Opinion and Order re: Preemption, In re Nat'l Prescription Opiate Litig., MDL No. 2804 (Sept. 3, 2019) (Dkt. No. 2565) at 22 ("Plaintiffs have not alleged a claim for fraud on a federal agency, . . . Plaintiffs' claims are not impliedly preempted under *Buckman* [*Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001)]."); *id.* at 9 ("Plaintiffs' marketing-based claims are not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman*.").

But Plaintiffs' due diligence-based claims—*i.e.*, those claims based on Distributors' alleged failure to report suspicious orders—do inherently assert a fraud on the DEA. Plaintiffs and their experts have said repeatedly that Distributors, by failing to report suspicious orders to

DEA, misled the agency, and, but for that deception, DEA and state and local authorities would have acted to police the excess prescribing of opioids. This is a classic fraud-on-the-agency argument, and impermissible under *Buckman*. In *Buckman*, the Supreme Court held that where federal agencies are endowed with the authority to detect, police, and prosecute suspected frauds against them—as DEA and FDA are—federal law impliedly preempts state law claims that rely on an alleged lack of candor or fraud in submitting required information to the agency. 531 U.S. at 347-53. "Lower courts have applied *Buckman*'s reasoning to other federal statutory schemes." *Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171 (D. Ariz. 2005) (collecting authorities). "Indeed, in every case where a court has analyzed whether a federal regulatory scheme preempts state law claims that require a plaintiff to prove as an essential element fraud on the federal agency responsible for administering the federal scheme, the court has found preemption of the state law claim." *Id.* at 1174.

Plaintiffs should be precluded from offering any testimony, evidence, or argument that Distributor Defendants have misled the DEA by failing to report suspicious orders, or otherwise failing to submit required information. This testimony, evidence, and argument would be irrelevant, prejudicial, and would risk confusing the jury. *See* Fed. R. Evid. 402, 403

6. [D-6] The Court Should Prohibit Counsel And Witnesses From Making References Broadly And Generally To "Defendants" When The Statement, Argument, Or Testimony Relates Only To Certain Specific Defendants Or Groups Of Defendants

Plaintiffs' claims in these cases rest on allegations that in many instances target only individual defendants or small subsets of the defendants. For example, Plaintiffs allege, repeatedly, that certain defendants deceptively marketed prescription opioids to doctors. Those allegations only implicate—indeed, *can* only implicate—the manufacturers. They do not involve the distributor defendants. Yet on this subject, among others, Plaintiffs and their witnesses are

routinely careless in speaking of alleged conduct by "defendants" without specifying about whom they are actually talking.

This carelessness can cause confusion, as was demonstrated in the expert report and deposition of Dr. Anna Lembke, one of Plaintiffs' experts. Dr. Lembke repeatedly referred to allegedly "misleading messaging by the *defendants*," *see* Lembke Tr. (Dkt. No. 1979-17) at 46:4, "false promotional statements on the part of *defendants*," (*id.* at 91:12-13), "misrepresentation of the evidence by the *defendants*," (*id.* at 223:9-10), and many similar statements. (Emphasis added). Later in the deposition when, pressed by attorney questioning, Dr. Lembke clarified that *none* of her references to "defendants" and the "industry" referred to the distributor or pharmacy defendants. (*Id.* at 267:25-268:11, 274:8-275:18.) In fact, Dr. Lembke had no opinions of any kind to offer about those defendants.

Such careless "lumping" violates Rule 403. The Court is entitled to exclude evidence if its probative value is substantially outweighed by danger of (1) unfair prejudice, (2) confusing the issues, (3) misleading the jury, (4) undue delay, (5) wasting time, or (6) needlessly presenting cumulative evidence. Fed. R. Evid. 403. There is no dispute that referring broadly to "defendants" rather than the proper subset has no probative value. On the converse, doing so poses all of the dangers Rule 403 was designed to prevent:

Unfair Prejudice: Attributing bad facts about "misrepresentation" and "misleading messaging" to parties that took no part in such actions, as Dr. Lembke did, risks unfairly prejudicing the jury against those parties.

Confusing the Issues or Misleading the Jury: "Lumping" can prevent a jury from properly allocating liability to individual defendants when they are entirely distinct entities. *Contra Rui He v. Rom*, No. 15–cv–1869, 2017 WL 1054814, at *5 (N.D. Ohio, Mar. 21, 2017)

(holding that "lumping" on jury form was not problematic because the jury "had no reason to allocate fault between the various Defendant Companies because they were a single, veil-less entity"). Where jurors must make distinctions between defendants, and evidence is presented in an undifferentiated manner, jurors are likely to be confused about *which* defendants are being discussed at any given time, and will be unable to attribute testimony or argument to the specific defendants to which it actually relates. *See Reo v. Caribbean Cruise Line, Inc.*, No. 14 CV 1374, 2016 WL 1109042, at *3 (N.D. Ohio, Mar. 18, 2016) (noting that a complaint using "Defendants" to refer to allegations against only some parties was "sloppy and mildly confusing").

Undue Delay, Wasting Time, or Cumulative Evidence: One of the many reasons "lumping" of parties is problematic is that it does not give individual defendants adequate notice of the charges against them. It is for this reason that "lumping" of parties in a complaint is a basis for dismissal under Rule 12(b)(6). *See Marcilis v. Township of Redford*, 693 F.3d 589, 596 (6th Cir. 2012) (affirming district court dismissal of complaint against two defendants whose conduct was not alleged with particularity); *see also Seri v. Crosscountry Mortgage, Inc.*, No. 16–cv–01214, 2016 WL 5405257, at *4 (N.D. Ohio, Sept. 28, 2016) (dismissing complaint in part because plaintiffs "lumped" defendants together and thereby failed to "give the defendant fair notice of what the claim is and the grounds upon which it rests.") (internal quotation marks omitted). "Lumping" at trial is even worse, because it forces individual defendants to use valuable court time to cross-examine witnesses to clarify how they are using "defendants," object to counsel's use of the generic term "defendants," or take the time to parse and counter what they said. If each individual defendant is forced repeatedly to stave off such misunderstandings, such

efforts will inevitably waste time, at best, and, most likely, will lead to ongoing and continuous confusion.

7. [D-7] The Court Should Preclude Plaintiffs From Offering Evidence Of, And Arguments About RICO Predicates That Plaintiffs Did Not Identify In Their Discovery Responses.

In an interrogatory, Distributors asked Plaintiffs to identify the "predicate acts" on which they rely in support of their RICO and OCPA claims. In response, Plaintiffs identified only (i) mail and wire fraud and (ii) purported false or fraudulent statements to DEA. *See* Plaintiffs' Supp. Responses to Distributor Defendants' Interrogatories 24, 25, 26, and 27, at 4. Accordingly, Plaintiffs should be barred from presenting evidence or argument that Distributors committed any predicate acts other than those timely identified in their Interrogatory Responses. *See Bridgeport Music, Inc. v. WM Music Corp.*, 508 F.3d 394, 400 (6th Cir. 2007) (holding that a plaintiff may not "expand its claims to assert new theories" at the summary judgment stage or beyond); *Vystrcil v. Mercy Health*, No. 17CV781, 2019 WL 2076035, at *4 (N.D. Ohio May 10, 2019) (holding that "Plaintiffs may not expand the scope of their claims" to allege violation of a different underlying statute on summary judgment (citing *Tucker v. Union of Needletrades, Indus., & Textile Emps.*, 407 F.3d 784 (6th Cir. 2005))); *see also Feinstein v. Resolution Tr. Corp.*, 942 F.2d 34, 42 (1st Cir. 1991) ("It is not enough for a plaintiff to file a RICO claim, chant the statutory mantra, and leave the identification of predicate acts to the time of trial.").

8. [D-8] The Court Should Issue An Order Excluding Any Evidence Of, Or Reference To, Distributor-Run Programs That Allowed Manufacturers To Communicate Product Information To Pharmacies Or Other Parties

The Court should issue an order excluding any evidence of, or reference to, Distributor-run programs that allowed manufacturers to communicate product information to pharmacies or other parties. Plaintiffs have expressly admitted that their claims do not in any way relate to

purported "marketing" by Distributors. *See* Dkt. No. 2182, at 82 (admitting that Distributors "did not join the Opioid Marketing Enterprise"). Given this unequivocal admission, Plaintiffs inclusion of many documents relating to these programs as trial exhibits is inexplicable. *See, e.g.*, P-8161; P-8165. All such documents, and any other reference to these programs, should be excluded as irrelevant, *see* Fed. R. Evid. 402, and because their admission would create a substantial and unavoidable risk of jury confusion and unfair prejudice, *see* Fed. R. Evid. 403.

Plaintiffs' RICO and OCPA claims against Distributors relate to an alleged "Supply Chain Enterprise" focused on alleged "eva[sion of] state and federal diversion controls" in the development and maintenance of their suspicious order monitoring programs. *See, e.g.*, Dkt. No. 2182 at 4. These claims in no way relate to the programs, offered by certain distributors, through which manufacturers provided basic product information to pharmacies and others.[16] To the contrary, Plaintiffs have alleged a ***separate*** "Marketing Enterprise" against manufacturers only. *Id.* at 1. Moreover, Plaintiffs have expressly disavowed any suggestion that these distributor-operated programs are relevant to their civil conspiracy claim and have admitted that the conspiracy claim is "*not based on opioid marketing*." *Id.* at 114 (emphasis added).[17] The program materials therefore are irrelevant. *See Sanco, Inc. v. Ford Motor Co.*, 771 F.2d 1081, 1087 (7th Cir. 1985) (affirming exclusion of evidence that only a supported a theory plaintiffs did not proceed under at trial); *Mendelsohn v. Sprint/United Mgmt. Co.*, 587 F. Supp. 2d 1201, 1217 (D. Kan. 2008), *aff'd*, 402 F. App'x 337 (10th Cir. 2010) (admissibility of evidence requires a showing that the evidence relates "to the plaintiff's circumstances and theory of the case").

[16] Plaintiffs own expert, Dr. Perri, acknowledges that the Distributor programs in question only provide price and availability information "to pharmacies and other buyers"—not prescribers—and "do not generate patient level demand." Perri Tr. (Dkt. No. 1983-4) at 218:17–219:6, 224:19-2.

[17] Even with respect to any marketing claims against manufacturers participating in the trial, any distributor programs involving those manufacturers are still irrelevant. Plaintiffs' claims against manufacturers relate to efforts to "drastically expand the market" for opioid medication by deceiving prescribers. *See, e.g.*, Summit TAC ¶¶ 1, 775; Cuyahoga TAC ¶¶ 1, 821. Distributors' programs did not do that. *See* n.16.

In light of Plaintiffs' admissions regarding relevance, the only possible purpose for Plaintiffs' inclusion of these materials on their exhibit list is to confuse the jury by blurring the distinction between Distributors and Manufacturers in an effort to have the jury assign blame for the alleged "Marketing Enterprise" to Distributors. *See Sidari v. Orleans Cnty.*, 174 F.R.D. 275, 282 (W.D.N.Y. 1996) ("A lumping together of such claims, which amounts to guilt by association, would unfairly prejudice the defendants."); *Deskovic v. City of Peekskill*, 673 F. Supp. 2d 154, 171 (S.D.N.Y. 2009) (recognizing the possibility of "spill-over" prejudice between claims brought against different defendants). The risk of confusion is particularly strong here where Plaintiffs acknowledge that the materials in question—unlike Manufacturers' very different marketing activities—had no impact on the "increased demand" for opioids that form the heart of their case against Manufacturers. *See supra* n.16.[18] In this incredibly time-compressed trial setting, where each Defendant has only limited time to address and respond to Plaintiffs' allegations, the possibility of jury confusion on these points is only heightened.

The Court should exclude trial exhibits relating to, or referencing, Distributor-run programs that allowed manufacturers to communicate their product information to pharmacies and other parties.

[18] While all such evidence and argument should be excluded, program materials involving the products of manufacturers that do not appear at trial are particularly objectionable. For those products, there is a substantial risk that the jury will be misled into holding Distributors to account for product information drafted, controlled, and warranted to be FDA-compliant by the manufacturers no longer at trial.

III. CONCLUSION

For the reasons stated above, Distributor Defendants request that the Court grant Defendants' Omnibus Motions in Limine.

Dated: September 25, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Robert A. Nicholas, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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